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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,660	11/29/2001	Paul James Davis	C7535(V)	7543

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PATENT DEPARTMENT  
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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/05/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/998,660

Applicant(s)

DAVIS ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/742,690.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 15 and 16 are currently pending in this application.

#### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

#### ***Drawings***

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 15 and 16 depend from a cancelled claim 1 thus rendering the above claims indefinite. (However, in order to expedite the prosecution of the above application, Examiner has incorporated the subject matter of claim 1 in claims 15 and 16 for further examination).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a detergent composition comprising a fusion protein comprising a cellulose binding domain (CBD) and a domain having high binding affinity for another ligand such as a specific antibody raised against a specific antigen (ligand), does not reasonably provide enablement for any detergent composition comprising any such fusion protein wherein the high affinity binding domain (HABD) is directed to any ligand. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 15-16 are so broad as to encompass detergent compositions and a method of using such composition comprising any fusion protein comprising a cellulose binding domain (CBD) and a domain having high binding affinity for any ligand with any binding equilibrium constant. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the detergent compositions comprising fusion protein comprising a CBD and a high affinity binding domain directed to a large number of so called ligands, for which there is no known methods for producing said HABDs. Furthermore even if such

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HABDs were available, claims are directed to the use of any such HABDs having any level of binding equilibrium. Applicants have first of all not demonstrated as to how one skilled in the art can obtain such HABDs, for example, a HABD for a "fabric or a specific part of a fabric or a micro-particle. There are no known methods in the art to make HABDs for any or all types of ligands and even if there were such methods, applicants have not taught all such methods. Therefore in order to make and use the above detergent composition, those skilled in the will require a knowledge of and guidance with regard to all methods of making such HABDs and using such HABDs to make fusion proteins. However, in this case the disclosure is silent regarding any such method.

While techniques to make antibodies against known antigens are known, it is not routine in the art to make HABDs against compounds whose chemical make up is unknown or uncertain.

The specification does not support the broad scope of the claims which encompasses detergent compositions comprising fusion proteins comprising a CBD and high binding affinity domain comprising any HABD against any ligand with any level of binding equilibrium, because the specification does not establish: (A) a rational and predictable scheme for making HABDs against any ligand whose chemical makeup is unknown; (B) a rational and predictable scheme for making fusion proteins using such HABDs; and (C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims directed broadly to any detergent composition comprising fusion proteins

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comprising a CBD and HABD directed to any ligand. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making the above detergent composition comprising the said fusion protein having the desired characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 15 and 16 are directed to detergent compositions comprising fusion proteins comprising CBD and HABDs directed towards any ligand and a method of using such detergent compositions. Claims 15 and 16 are rejected under this section of 35 USC 112 because the claims are directed to detergent composition comprising a genus of polypeptides including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution and fragments that have not been disclosed in the specification. No description has been provided of the modified polypeptide sequences encompassed by the claim. No information, has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the structure of all HABDs in the fusion protein (apart from the CBD sequences) including fragments and variants within the scope of the claimed genus. The genus of polypeptides

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claimed is a large variable genus including peptides which can have a wide variety of structure. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 15-16 are rejected under 35 U.S.C. 102(a) as anticipated by Bettiol et al. (WO 99/57155, Nov. 1999). This rejection is based upon the public availability of a printed publication. Claims 15-16 of the instant application are drawn to a detergent composition comprising a fusion protein comprising CBD and a domain having a high binding affinity for another ligand and a process of delivering a benefit agent such as softening agent, finishing agent/protective agent, fragrances or bleaching agents to a fabric by treating the fabric with a composition comprising said fusion protein.

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Bettiol et al. disclose detergent compositions comprising a fusion protein, comprising a CBD and an anti-microbial enzyme or a peptide wherein the anti-microbial enzyme or peptide has a high affinity to another ligand and both the domains are linked through an amino acid linker region. The reference also discloses the use of benefit agents such as surfactants or bleaching agents or protective agent (anti-microbial enzyme) in detergent compositions used for treating fabrics. While the reference does not explicitly teach a "process for delivering a benefit agent to a fabric" by treating said fabric with a composition comprising the fusion protein, the reference discloses the use of such composition --to clean fabrics-- which encompasses the embodiments of claim 16. Therefore Bettiol et al. anticipate claims 15-16 as written.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent application Nos. 09/742,694 and 09/742,693. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct



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from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 16 of the instant application and claims 1, 3 of the reference application are both directed to method of delivering a benefit agent to a fabric by treating it with a composition comprising the binding molecule wherein the binding molecule is a fusion protein comprising a cellulose binding domain and a domain having a high binding affinity to another ligand. In the methods claimed in the instant application and in the reference application there are identical steps and materials (i.e., fusion protein) used. The portion of the specification (and the claims) in the instant application that supports the recited method includes embodiments that would anticipate the specific method claimed in claims 1 and 3 of the reference application. Claim 16 of the instant application listed above cannot be considered patentably distinct over claims 1, 3 of the reference application when there is specifically recited embodiment that would anticipate mainly claim 16 of the instant application. Alternatively, claim 16 cannot be considered patentably distinct over claims 1, 3 of the reference application when there is specifically disclosed embodiment in the reference application that supports claims 1, 3 of that application and falls within the scope of claim 16 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1, 3 of the reference by making it more broader. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1, 3 of the reference application.

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Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent application No. 09/742,689. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 16 of the instant application and claims 1, 9 of the reference application are both directed to method of delivering a benefit agent to a fabric by treating it with a composition comprising the binding molecule wherein the binding molecule is a fusion protein comprising a cellulose binding domain and a domain having a high binding affinity to another ligand. In the methods claimed in the instant application and in the reference application there are identical steps and materials (i.e., fusion protein) used. The portion of the specification (and the claims) in the instant application that supports the recited method includes embodiments that would anticipate the specific method claimed in claims 1 and 9 of the reference application. Claim 16 of the instant application listed above cannot be considered patentably distinct over claims 1, 9 of the reference application when there is specifically recited embodiment that would anticipate mainly claim 16 of the instant application. Alternatively, claim 16 cannot be considered patentably distinct over claims 1, 9 of the reference application when there is specifically disclosed embodiment in the reference application that supports claims 1, 9 of that application and falls within the scope of claim 16 herein because it would have been

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obvious to one having ordinary skill in the art to modify claims 1, 9 of the reference by making it more broader. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1, 9 of the reference application.

### *Conclusion*

None of the claims are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

  
MANJUNATH RAO  
PATENT EXAMINER

Manjunath N. Rao, Ph.D.  
May 1, 2003